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09/988,899	11/19/2001	Hendricus Renerus Jacobus Mattheus Hoogenboom	DX/003 CON	9170

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT PAPER NUMBER

1639

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,899

Applicant(s)

HOOGENBOOM, HENDRICUS
RENERUS JACOBUS M

Examiner

Padmashri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment and response filed on 10/6/04 has been fully considered and entered into the application. The amendment filed on 10/6/04 cancels claim 10 , and adds new claims 11-16.
2. Claims 4-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed on 1/9/04.
3. This application contains claims 4-9 drawn to an invention nonelected with traverse in Paper filed on 1/9/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. Claims 1-3 and 10-16 are currently being examined in this application.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Europe on 5/18/99.
6. Receipt is acknowledged of papers submitted on 12/2/04 under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Withdrawn Claim Rejections

7. The objection of claim 10 set forth in the previous office action has been withdrawn in view of cancellation of the claim.
8. The rejections of claims 1-3 as lacking antecedent basis set forth in the previous office action has been withdrawn in view of the amendments to the claims.
9. The rejection of claims 1-3, 10 as being anticipated by WO 9405781 has been withdrawn in view of the amendments.

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10. The rejection of claims 1-3 and 10 as being anticipated by EP 844306 A1 (reference provided by applicants in PTO 1449 filed on 5/25/02) is withdrawn in view of filing of the priority documents.

11. The rejections of claims 1-3 and 10 as being anticipated by US Patent 5,969,108 (note the instant application does not get the priority date of the EP application.) is withdrawn in view of filing of the priority documents.

12. The rejection of claims 1-3 and 10 as being anticipated by US Patent 6,172,197 B1, set forth in the previous office action has been withdrawn in view of the amendments.

(NOTE the art rejections over EP 844306 A1, US Patent 5,969,108 and 6,172,197 have been rewritten to address the newly added limitations)

New Claim Rejections Necessitated by the Amendment

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 1-3, 11-16 are rejected under 35 U.S.C. 102(a) as being anticipated by EP 844306 A1 (reference provided by applicants).

The instant claims briefly recite a library of vectors comprising, a) first and second

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cloning region comprising unique restriction enzyme cleavage site, a ribosome binding site and a signal sequence, b) a polynucleotide encoding anchor region, c) a first and second variable antibody regions, and d) a polynucleotide encoding a tag.

EP 844306 A1 teaches methods for producing members of specific binding pairs. The reference teaches DNA encoding a genetically diverse population of specific binding pairs in recombinant host cells. The reference teaches that the recombinant genetic packages (refers to the vectors of the instant claims). The reference teaches a library of 10^{14} possible clones expressing the combination of H and L chain (refers to instant claims 3, 11-16) (e.g., see page 6). The reference vector comprises rbs at the 5' end of cloning regions, restriction enzyme sites and first and second cloning regions comprising Vh and Vl antibody fragments, gIII at the 3' end of the second cloning region (e.g., see figure 27). The reference teaches that the vector has a sequence encoding a C-terminal peptide tag for detection (reads on the instant claim tag) (i.e., see page 46). The reference clearly anticipates the claimed invention.

15. Claims 1-3, 11-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,969,108 (McCafferty et al) (filing date Jan 1993).

The instant claims briefly recite a library of vectors comprising, a) first and second cloning region comprising unique restriction enzyme cleavage site, a ribosome binding site and a signal sequence, b) a polynucleotide encoding anchor region, c) a first and second variable antibody regions, and d) a polynucleotide encoding a tag.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

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CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

McCafferty et al teach methods for producing members of specific binding pairs. The reference teaches DNA encoding a genetically diverse population of specific binding pairs in recombinant host cells. The reference teaches that the recombinant genetic packages (refers to the vectors of the instant claims). The reference teaches a library of 10^{14} possible clones expressing the combination of H and L chain (refers to instant claim 3) (e.g., see column 6). The reference teaches vectors (or genetic packages) comprising from 5' to 3', rbs-enzyme cleavage site, vH –rbs-enzyme cleavage site-vL-N' terminus of gene III (e.g., see figure 45). The reference teaches that the vector has a sequence encoding a C-terminal peptide tag for detection (i.e., see column 63, figure 26). Thus the reference clearly anticipates the claimed invention.

16. Claims 1-3, 11-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,172,197 B1 (McCafferty et al)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

McCafferty et al teach methods for producing members of specific binding pairs. The reference teaches DNA encoding a genetically diverse population of specific binding pairs in

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recombinant host cells. The reference teaches that the recombinant genetic packages (refers to the vectors of the instant claims). The reference teaches a library of 10^{14} possible clones expressing the combination of H and L chain (refers to instant claim 3) (e.g., see column 6). The reference teaches vectors (or genetic packages) comprising from 5' to 3', rbs-enzyme cleavage site, vH –rbs-enzyme cleavage site-vL-N' terminus of gene III (e.g., see figure 45). The reference teaches that the vector has a sequence encoding a C-terminal peptide tag for detection. Thus the reference clearly anticipates the claimed invention.

Response to Arguments

17. Applicant's arguments with respect to claims 1-3, 11-16 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments regarding the rejections over EP 844306 A1, US Patent 5,969,108, and 6,172,197 (McCafferty et al) have been considered. Even though the rejection has been rewritten, examiner would like to address some of the arguments.

Applicants argue that in McCafferty invention, the properties of one of the polynucleotides are known and kept fixed. Applicant's arguments have been considered and are not persuasive because, the instant claim do not recite that the polynucleotides are unknown and the reference teaches in the library one of the polypeptide is fixed, but the polynucleotide can be variable. Further in the instant claim the vectors in the library each have a different polynucleotide as in applicant's arguments. Applicants further argue that the vector comprises first and second cloning region, and the reference do not teach two cloning regions. Applicants arguments are not persuasive, since Sfi and Not I site are considered as two cloning regions. Thus, the references clearly anticipate the claimed invention.

Conclusion

18. No claims are allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


PADMASHRI PONNALURI
PRIMARY EXAMINER

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

18 February 2005